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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/664,363	09/18/00	HIGHFIELD	P 2035-38

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HM12/0420

EXAMINER

LI, B

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED:

04/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/664,363

Applicant(s)

HIGHFIELD ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions groups is required under 35 U.S.C. 121:

- I. Claims 1-6, 19 and 20, drawn to a subcombination PT-NANBH viral polypeptide and method of using the polypeptide, classified in class 424, subclass 228.1 .
- II. Claims 7-8, 19 and 20, drawn to a combination PT-NANBH viral polypeptide and a method of using the polypeptide, classified in 424, subclass 205.1.

Upon election of Group II, Applicant is additionally required to elect one polypeptide to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

- (1). The polypeptide encoded by SEQ.ID. NO.5 and SEQ. ID. NO. 3.
 - (2). The polypeptide encoded by SEQ.ID. NO.5 and SEQ. ID. NO. 4.
- III. Claims 9-13, drawn to a DNA sequence encoding the subcombination PT-NANBH viral polypeptide and a method for using the DNA sequence as a vector to transform a cell line, classified in 536, subclass 23.72.
 - IV. Claim 14, drawn to an antibody against a subcombination PT-NANBH viral polypeptide, classified in 424, subclass 139.1.
 - V. Claim 15, drawn to a method for detecting PT-NANBH viral nucleic acids, classified in 204, subclass 469.
 - VI. Claim 16, drawn to a kit for detecting PT-NANB viral nucleic acids, classified in 435, subclass 975.
 - VII. Claim 17, drawn to a method for detecting PT-NANBH viral antigen or antibody and a kit used by the method, classified in 435, subclass 7.1.
 - VIII. Claim 18, drawn to a kit for detecting PT-NANB viral antigen or antibody, classified in 435, subclass 975.

Upon election of Group I, III-VIII, Applicant is additionally required to elect a single sequence to be examined on the merits. This requirement is not to be construed as a

requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

- a). Sequence of the polypeptide is SEQ. ID. NO. 3.
- b). Sequence of the polypeptide is SEQ. ID. NO. 4.
- c). Sequence of the polypeptide is SEQ. ID. NO. 5.
- d). Sequence of the polypeptide is SEQ. ID. NO. 18.
- e). Sequence of the polypeptide is SEQ. ID. NO. 19.
- f). Sequence of the polypeptide is SEQ. ID. NO. 20.
- g). Sequence of the polypeptide is SEQ. ID. NO. 21.
- h). Sequence of the polypeptide is SEQ. ID. NO. 22.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different products and produce different biological effects, e.g. the product of the Group I and III differs in molecular structure between the amino acids and nucleic acids.

Inventions of Group V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group V and VII are directed to two different methods. They are not disclosed as capable use together, they work in different modes, and produce different biological effect.

Inventions Group I and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the product of the Group I can be used in a material different process, such as induction of an immune response.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

1. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 5:00.

4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

5. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

Bao Qun Li
April 10, 2001

Ans
ALI R. SALAM
PRIMARY EXAMINER